

4. 510(k) Summary

SEP 15 2006

This summary of safety and effectiveness is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.87.

Establishment Registration Number: 2021898

Address of Manufacturer: Medtronic Neurosurgery
125 Cremona Drive
Goleta CA, 93117
(805) 968-1546 ext. 1773
Fax: (805) 968-9336

Contact Person: Jeffrey Henderson

Date: March 10, 2006

Trade or Proprietary Name: Medtronic PS Medical® Strata® Type Valve

Common usual or Classification Name: Central Nervous System Flow Control Shunts and Accessories (882.5550)

Predicate Device Identification: K012052 - Medtronic PS Medical® Strata® Valve
K033850 - PS Medical® Strata® NSC Valve
K040943 - Strata® Valve Adjustment and Indicator Tools
K042465 - PS Medical® Strata® II Valve

Description: The Medtronic PS Medical® Strata® Type Valve is an adjustable valve designed for non-invasive pressure-flow adjustment.

Intended Use of the device and the predicate device(s): The intended use of the Medtronic PS Medical® Strata® Type Valve in this submission is substantially equivalent to those previously cleared under K012052, K042465, and K033850.

The Medtronic PS Medical® Strata® Valve and Strata® NSC Valve are shunt components designed to provide continued Cerebrospinal Fluid (CSF) flow from the ventricles of the brain into the right atrium of the heart or peritoneal cavity. The design allows the physician to non-invasively adjust valve pressure/performance level pre- and post-implantation by using an external magnetic adjustment tool without the need for radiographic confirmation.

The Medtronic PS Medical® Strata® II Valve and shunt assemblies with and without BioGlide are shunt components designed to provide continued CSF flow from the ventricles of the brain into the right atrium of the heart or the peritoneal cavity. The design allows the physician to non-invasively adjust valve pressure/performance level pre- and post-implantation by using a special magnetic adjustment tool without the need for radiographic confirmation.

Technological comparison: Medtronic Neurosurgery submits that the materials of fabrication, intended use, and the fundamental scientific technology of the Medtronic PS Medical® Strata® Type Valves are the same as the previously reviewed and cleared Strata-type valves. Based upon the summary above, Medtronic Neurosurgery determines substantial equivalence, safety, and efficacy of the Medtronic PS Medical® Strata® Type Valves compared to the predicate and currently marketed devices.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Medtronic Neurosurgery
% Mr. Jeffrey Henderson
Vice President, Quality &
Regulatory Affairs
125 Cremona Drive
Goleta, California 93117-5500

Re: K060681

Trade/Device Name: Medtronic Neurosurgical Implants
Regulation Number: 21 CFR 882.5550
Regulation Name: Central nervous system fluid shunt and components
Regulatory Class: II
Product Code: JXG
Dated: August 15, 2006
Received: August 16, 2006

Dear Mr. Henderson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

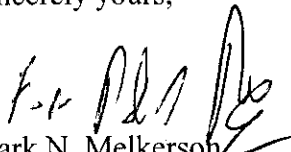
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forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,


Mark N. Melkersen
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

II. Statement of Indications for Use

510(k) Number (if known): K060681

Device Name: Medtronic Neurosurgical Implants

Indications for Use:

Medtronic PS Medical® Strata® Valve and Strata® NSC Valve

The Medtronic PS Medical® Strata® Valve and Strata® NSC Valve are shunt components designed to provide continued Cerebrospinal Fluid (CSF) flow from the ventricles of the brain into the right atrium of the heart or peritoneal cavity. The design allows the physician to non-invasively adjust valve pressure/performance level pre- and post-implantation by using an external magnetic adjustment tool without the need for radiographic confirmation.

Medtronic PS Medical® Strata® II Valve

The Medtronic PS Medical® Strata® II Valve and shunt assemblies with and without BioGlide are shunt components designed to provide continued CSF flow from the ventricles of the brain into the right atrium of the heart or the peritoneal cavity. The design allows the physician to non-invasively adjust valve pressure/performance level pre- and post-implantation by using a special magnetic adjustment tool without the need for radiographic confirmation.

Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

K060681
Concurrence of [Signature] Office of Device Evaluation (ODE)
(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

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